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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/978,382	10/15/2001	Martin F. Yanofsky	19452A-000930US	4575

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EXAMINER

MEHTA, ASHWIN D

ART UNIT PAPER NUMBER

1638

DATE MAILED: 02/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/978,382

Applicant(s)

YANOFSKY ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: _____

DETAILED ACTION

Priority

1. The sentence on page 1, lines 4-7, indicates that the instant application claims the benefit of U.S. Provisional Application 60/090,649, filed June 25, 1998. However, the instant application was filed one October 15, 2001, which is more than one year after the provisional application was filed. In the paper received 01 February 2002, Applicants submitted an amendment to correct the priority. However, that amendment, to replace the paragraph on page 1, lines 4-7, was not entered because a marked-up version of the amendment was not submitted. Applicants should submit this amendment again, accompanied by a marked-up version showing the changes that were made. See 37 CFR 1.121. The amendments to claims 25, 27, 36, 38, 42, and 44, submitted in the same paper, were entered.

Drawings

2. The brief description to Figure 2 on page 9 indicates that this figure has parts A-D. However, these parts are not labeled on the figure. The figure should be amended by inserting these labels.

Similarly, the brief description to Figure 5 indicates that this figure has parts A and B. However, the parts are not labeled on the figure. The brief description of Figure 5B on page 10 also indicates that parts within it are labeled (a)-(f), which also do not appear in the figure. The figure should be amended by inserting these labels.

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Figure 8 shows the nucleotide sequences and corresponding amino acid sequences of Arabidopsis AGL1 and AGL5. However, it is not clear from the figure, which sequences are AGL1 and which are AGL5. The figure should be amended to more clearly identify the AGL1 sequences from the AGL5 sequences.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may **NOT** be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Applicant is required to submit a proposed drawing correction in reply to this Office action. However, formal correction of the noted defect may be deferred until after the examiner

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has considered the proposed drawing correction. Failure to timely submit the proposed drawing correction will result in the **ABANDONMENT** of the application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 24, 25, 27, 29-36, 38, 41, 42, 44, and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any method of enhancing lignification in a vascular plant, comprising any manner of ectopically expressing any nucleic acid molecule encoding any AGL1/5-like gene product in said plant; or said method wherein AGL1/5-like gene product comprises any polypeptide sequence at least 50% identical to SEQ ID NO: 4 or SEQ ID NO: 6; or wherein said method comprises introducing an exogenous nucleic acid molecule encoding an AGL1/5-like gene product into said plant, or wherein said exogenous nucleic acid is operatively linked to any exogenous regulatory element, or any tissue-selective regulatory element, or any AGL1 or AGL5 regulatory element; a transgenic vascular plant characterized by enhanced lignification, comprising an ectopically expressed nucleic acid molecule comprising a

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lignified tissue-selective regulatory element operatively linked to a nucleic acid molecule encoding any AGL1/5-like gene product.

The specification indicates that the Arabidopsis AGL1 and AGL5 genes encode MADS box proteins that share 85% identity at the amino acid level (page 42, lines 9-10). The nucleotide and amino acid sequences of AGL1 are set forth in SEQ ID NOs: 3 and 4, respectively. The nucleotide and amino acid sequences of AGL5 are set forth in SEQ ID NOs: 5 and 6, respectively. The specification also indicates that AGL1 and AGL5 share 100% identity in the MADS domain, 92% identity in the K-domain, 95% identity in the I domain, and 72% identity in the C domain (Tables 1 and 2, pages 42-43). The specification teaches that transgenic Arabidopsis plants were made that comprised either the Arabidopsis AGL1 or AGL5 coding sequences, or both, each operatively linked to the CaMV 35S promoter. Transgenic plants expressing both coding sequences displayed ectopic lignification of the valve mesophyll layers of fruit (Example IV, pages 69-71).

However, the specification does not describe nucleotide or amino acid sequences of other AGL1/5-like genes or gene products. The specification does not describe any other structures that have the same functional activity of causing enhanced lignification when expressed in a transgenic vascular plant. The specification teaches that AGL1/5-like proteins comprise a MADS domain and domains termed "I," "K," and "C." However, other proteins have these domains as well. For example, as is clear from the specification, AGL8 comprises these domains, yet AGL8 is not the same protein as AGL1 or AGL5. Therefore, the presence of these domains alone does not correlate a protein with the functional activity of AGL1/5 proteins. Further, all polypeptide sequences that share greater than 50% identity with SEQ ID NOs: 4 or 6

will not also share its functional activity. For example, Liu et al. (Plant Sci., 1999, Vol. 142, pages 73-82) teach an amino acid sequence from sweetgum that has 68.3% identity with instant SEQ ID NO: 4 and 68% identity with instant SEQ ID NO: 6, but is an AGAMOUS homolog, not AGL1 or AGL5. Further, Boss et al. (Plant Mol. Biol., 2001, Vol. 45, pages 541-553) teach that various MADS box genes have roles in different processes, such as flower development, fruit development, root branching, and assert that sequence homology alone is not a clear indicator of MADS box gene function (page 542). The specification then does not correlate that structures of amino acid sequences that share as little as 50% identity with SEQ ID NOs: 4 or 6 with their functions. The specification also does not describe the sequences of any AGL1/5 promoters. The nucleotide sequences set forth in SEQ ID NOs: 3-6 do not provide any information concerning the structures of the Arabidopsis AGL1 or AGL5 gene promoters, or AGL1/5 genes of other species. Given the breadth of the claims encompassing nucleic acid molecules encoding all AGL1/5-like gene products, and the lack of written description as discussed above, the specification fails to provide an adequate written description of the multitude of nucleic acid molecules encompassed by the claims.

4. Claims 24-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are broadly drawn towards any method of enhancing lignification in a vascular plant, comprising any manner of ectopically expressing any nucleic acid molecule

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encoding any AGL1/5-like gene product in said plant; or wherein the AGL1/5-like gene product comprises any polypeptide sequence at least 50% identical to SEQ ID NO: 4 or SEQ ID NO: 6 or has the polypeptide sequence of SEQ ID NO: 4 or 6; or wherein said method comprises introducing an exogenous nucleic acid molecule encoding an AGL1/5-like gene product into said plant, or wherein the AGL1/5-like gene product comprises any polypeptide sequence at least 50% identical to SEQ ID NO: 4 or SEQ ID NO: 6 or has the polypeptide sequence of SEQ ID NO: 4 or 6, or wherein said exogenous nucleic acid is operatively linked to any exogenous regulatory element, or any tissue-selective regulatory element, or any AGL1 or AGL5 regulatory element; a transgenic vascular plant characterized by enhanced lignification, comprising an ectopically expressed nucleic acid molecule comprising a lignified tissue-selective regulatory element operatively linked to a nucleic acid molecule encoding any AGL1/5-like gene product.

The specification indicates that the Arabidopsis AGL1 and AGL5 genes encode MADS box proteins that share 85% identity at the amino acid level (page 42, lines 9-10). The nucleotide and amino acid sequences of AGL1 are set forth in SEQ ID NOs: 3 and 4, respectively. The nucleotide and amino acid sequences of AGL5 are set forth in SEQ ID NOs: 5 and 6, respectively. The specification also indicates that AGL1 and AGL5 share 100% identity in the MADS domain, 92% identity in the K-domain, 95% identity in the I domain, and 72% identity in the C domain (Tables 1 and 2, pages 42-43). The specification teaches that transgenic Arabidopsis plants were made that comprised either the Arabidopsis AGL1 or AGL5 coding sequences, or both, each operatively linked to the CaMV 35S promoter. Transgenic plants expressing SEQ ID NO: 3, or both coding sequences, displayed ectopic lignification of the valve mesophyll layers of fruit (Example IV, pages 69-71).

However, the specification does not teach other AGL1/5 gene products other than SEQ ID NOs: 4 and 6. The specification teaches that the AGL1/5 gene products comprise a MADS domain and I, K, and C domains. However, the presence of these domains alone does not indicate that a protein is an AGL1/5 polypeptide. As discussed above, Boss et al. teach that various MADS box genes have roles in different processes, such as flower development, fruit development, root branching, and assert that sequence homology alone is not a clear indicator of MADS box gene function. Also as discussed above, Liu et al. (Plant Sci., 1999, Vol. 142, pages 73-82) teach an amino acid sequence from sweetgum that has 68.3% identity with instant SEQ ID NO: 4 and 68% identity with instant SEQ ID NO: 6, but is an AGAMOUS homolog, not AGL1 or AGL5. The specification does not teach how the sequences set forth in SEQ ID NOs: 4 and 6 may be changed without altering its function. In the absence of further guidance, undue experimentation would be required by one skilled in the art to determine how the sequences of SEQ ID NOs: 4 and 6 may differ without altering their functional activities. Also see In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 USPQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein. Further, the specification also does not teach any AGL1 or AGL5 gene promoters. The coding sequences of Arabidopsis AGL1 and AGL5 in SEQ ID NOs: 3 and 5 do not provide any information concerning the sequences of their promoters, or those of other AGL1/5 genes.

As discussed above, the specification teaches that transgenic Arabidopsis plants expressing the AGL1 coding sequence (SEQ ID NO: 3) or both the AGL1 and AGL5 (SEQ ID NO: 5) coding sequences displayed lignification of the valve mesophyll layers of fruit (Example

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IV, pages 69-71). However, the specification does not teach that transgenic plants ectopically expressing only AGL5 displayed any enhanced lignification of any plant part, as encompassed by the claims. The specification states, in the sentence bridging pages 70-71, that 35S::AGL5 fruits appeared identical to that of wild type fruits. In light of this data, undue experimentation would be required by one skilled in the art to use the claimed method to enhance lignification in any vascular plant by causing the ectopic expression of an AGL5-like gene product.

Further, the specification does not teach any other method of causing the ectopic expression of any AGL1/5-like gene product other than by introduction of an exogenous nucleic acid molecule that encodes an AGL1/5-like gene product. The specification does not teach how the expression of AGL1/5-like genes are controlled in plants, and examples of such regulation are lacking in the prior art. In the absence of further guidance, it would require undue experimentation by one skilled in the art to determine the regulators of AGL1/5-like genes or gene products, or to determine other methods in which AGL1/5 like gene products can be ectopically expressed. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Furtherstill, the specification does not teach that lignification was increased in any other plant part in the transgenic Arabidopsis plants transformed with SEQ ID NO: 3, or both SEQ ID NOs: 3 and 5, other than in the valve mesophyll layers of fruit, even though the coding sequences were operatively linked to the constitutive CaMV 35S promoter. Given theses teachings, the claimed method apparently does not result in the lignification of any other plant part. Furthermore, it is not clear how one skilled in the art is to use such plants, in which the

- don't have
data - they
only looked
at lignification

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valve mesophyll layer of fruit have increased lignification. The specification teaches that enhanced lignification can be desirable for greater wind or water resistance, increased resistance to pathogens, and, in the case of woody plants, increases in heat content for direct utilization as fuel (paragraph bridging pages 53-54). However, it is not clear how these uses relate to the valve mesophyll layer of fruit. The specification teaches that fruit of 35S::AGL1 35S:: AGL5 transgenic plants tear open due to seed crowding (sentence bridging pages 9-10). However, this is not a desirable property. Yanofsky et al. (U.S. Patent No. 6,288,305) teach that this "seed shattering" is a significant problem that leads to a considerable loss of seed yield and income to the seed industry (col. 1, lines 40-52). It is then not clear how one skilled in the art is to use the claimed transgenic plants produced by the claimed method. Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

forms
outer
coating
for to be
providing
AGL5
AGL5
AGL5
resistance

5. Claims 24-47 are rejected.


Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this

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application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Customer Service receptionist for Technology Center 1600, whose telephone number is 703-308-0196.

February 6, 2003


ASHWIN D. MEHTA, PH.D
PATENT EXAMINER